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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,722	01/17/2002	Hiroshi Yanagawa	2001-1921	3316

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WASHINGTON, DC 20006-1021

EXAMINER
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LAMBERTSON, DAVID A

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 04/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/046,722

Applicant(s)

YANAGAWA ET AL.

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION:

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 22-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/284,627.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed October 14, 2004.

Amendments were made to the claims.

Claims 22-30 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed July 1, 2004, that is not addressed in this action has been withdrawn.

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority under 35

U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. 09/284,627 (now US Patent 6,361,943), filed on June 2, 1999.

It is noted that Applicant relies on page 40, lines 10-24 of the instant specification for support for the instant amendment to the claims. This section of the instant specification involves the production of RNA molecules from a gene library or cDNA library. However, a review of the English translation of the foreign priority application (Japan 8-274855; translation prepared by Yoshiyuki Kawaguchi) shows that this paragraph is not present, nor is there any clear support for producing RNA molecules from a gene library or cDNA library in the foreign application. As a result, foreign priority cannot be granted, thus the effective priority date of the instant specification is given only to October 17, 1997, the date of filing of the International Application from which the instant specification claims priority.

***Information Disclosure Statement***

The information disclosure statement filed February 8, 2005 has been considered, and a signed and initialed copy of the Form PTO-1449 is attached to this Office Action.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-28 and 30 are rejected under 35 U.S.C. 102(e) as being anticipated by Szostak *et al.* (IDS reference AC; see entire document; henceforth Szostak).

Szostak teaches a population of candidate RNA molecules comprising a pause sequence (i.e., a non-RNA moiety) covalently bonded to the 3'-end of an RNA molecule, wherein a population represents more than one molecule (i.e., a library) and the pause sequence comprises a peptide acceptor attached to a DNA or DNA analog sequence (see for example column 3, lines 27-34 and column 4, lines 63-65). Szostak also teaches that the RNA molecules can comprise mRNA sequences (see for example column 1, lines 63-66). Szostak gives a few specific examples of pause sequence, which include DNA substituted with  $\text{HO}(\text{CH}_2\text{CH}_2\text{O})_3\text{PO}_2$ , which are polyethylene glycol residues (see for example column 35, line 66 to column 36, line 2). Szostak also teaches hybridizing the "linker" region (i.e., the pause sequence, or non-RNA moiety) with a complementary oligonucleotide (this necessarily includes both DNA and RNA,

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given the art-accepted definition of oligonucleotide), thereby leading to the formation of double-stranded chains of DNA-DNA and DNA-RNA on the non-RNA moieties (see for example column 35, lines 64-66). As a result, Szostak anticipates the instantly rejected claims.

Applicant is advised that a declaration of interference is required to overcome the instant rejection. Applicant is referred to the rules on declaration of an interference for establishing a declaration of an interference. See especially 37 CFR §§ 1.605, 1.607 and 1.608, as well as all other relevant sections.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-28, 30 and 29\* rejected under 35 U.S.C. 103(a) as being unpatentable over Szostak (as applied to claims 22-28 and 30 under 35 USC § 102(e)) in view of Wittung *et al.* (*FEBS Letters* 365: 27-29, 1995; see entire document; henceforth Wittung). Note-\* represents the claim instantly rejected by the combination of references.

Szostak teaches all of the elements set forth above in the rejection of claims 22-28 and 30. Specifically, the production of RNA molecules from a library, wherein the RNA molecules comprise an RNA molecule covalently bonded at its 3' end to a non-RNA moiety, including DNA and DNA analogs.

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Wittung teaches that natural oligonucleotides are rapidly degraded, and that oligonucleotide analogs, such as PNA, offer more stability to the oligonucleotide sequence (see for example page 27, first paragraph).

It would have been obvious to combine the teachings of Szostak and Wittung because Szostak gives explicit instruction that any DNA analog can be used in their invention, and Wittung offers teachings regarding a particular type of DNA analog, PNA. The ordinary skilled artisan would have been motivated to combine the teachings of Szostak and Wittung because, as Wittung teaches, PNA offers more stability against degradation than does natural oligonucleotides such as DNA or RNA, thereby offering the advantage of increased stability and effectiveness to the molecules taught by Szostak. Absent evidence to the contrary, the ordinary skilled artisan would have had a reasonable expectation of success when combining the teachings of Szostak and Wittung.

***Allowable Subject Matter***

No claims are allowable.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.  
AU 1636



JAMES KETTER  
PRIMARY EXAMINER